DISCUSSION OF THE AMENDMENT

Claims 1-6 and 8-18 are active in the present application. Claim 7 is a canceled claim. Claims 11-18 are new claims. Support for new Claims 11-13 is found on page 2, lines 6-18. Support for new Claims 13 and 14 is found on page 4, lines 30-38. Support for new Claim 15 is found on page 8, lines 35-38. Independent Claim 1 has been amended to further define the inhibitor. Support for new Claim 16 is found on page 2, lines 6-11. Support for new Claim 17 is found on page 3, lines 16-33. Support for new Claim 18 is found in the original claims. No new matter is added.

REMARKS

Polyurethanes are known to undergo degradation and release amine compounds (page 1, lines 23-38 of the specification). The degree of degradation and the degree of amine formation is related, at least in part, to the catalyst present during the formation of the polyurethane resin (see the paragraph bridging pages 1 and 2). Inhibitors may be added to polyurethanes to improve resistance to degradation and amine formation (see page 2, lines 6-31). Inhibitors may however react with polymerization catalysts and thereby lead to the formation of a defective network structure in the polyurethane material (see page 2, lines 24-31).

Applicants have disclosed that embedding (e.g., encapsulating) an inhibitor in a substance that is inert to polyurethane polymerization reaction conditions stops the inhibitor from interfering with the polymerization reaction.

The Office rejected Claims 1-6 and 8-10 on the grounds that the claims are not enabled. The Office supported the rejection with nothing more than an conclusory statement. The Office carried out no analysis and provided no comprehensible technical reason why the original claims are not enabled. Applicants therefore submit that the rejection under 35 U.S.C. § 112, first paragraph is not supportable and should be withdrawn.

In order to expedite the prosecution, Applicants amend Claim 1 to include the inhibitors of Claim 7. Applicants submit that the amendment to Claim 1 overcomes the rejection at least because original Claim 7 was not rejected on the same ground.

The Office also rejected the claims under 35 U.S.C. § 112, second paragraph, on the grounds that the claims do not define and/or enable the term "inhibitor". Applicants submit that this ground of the rejection appears to completely ignore the disclosure of the original specification at, for example, page 2, lines 6-18. The aforementioned disclosure cites the use of inhibitors in polyurethane polymerization reactions and gives explicit examples of the

particular chemical materials that may be used as inhibitors. Applicants submit that those of ordinary skill in the art can easily understand the term "inhibitor" in view of the disclosure of the original specification and that an explicit definition in the claim is not necessary. In this regard, Applicants draw the Office's attention to new dependent Claim 16 which states that the inhibitor is a polyurethane degradation inhibitor.

The rejection is therefore not supportable and should be withdrawn.

The Office also appears to be of the belief that the term "wax" is not enabled and/or indefinite. Applicants draw the Office's attention to page 3, line 16 through page 5, line 38 which provides a detailed description of the waxes that may be used in the invention. The Office states that the description at page 13, lines 16-17 of the specification is in conflict with the ordinary meaning of the term "wax". However, the Office provides no support for this assertion and provides no alternate meaning for the term "wax". Further, the Office did not provide any reasons why the aforementioned description is in conflict with the generally accepted meaning of the term "wax". The Office merely provided a conclusory statement without any verifiable or supportable basis.

The rejection is therefore not sustainable and should be withdrawn.

The Office rejected the claims as anticipated in view of a patent to Hall (U.S. 4,670,483). Applicants submit that the disclosure of Hall cannot anticipate the presently claimed invention because Hall does not disclose an encapsulated or embedded inhibitor. Instead, Hall discloses an ammonium polyphosphate. Applicants submit that ammonium polyphosphate is not an inhibitor such as the inhibitors of the present claim.

Applicants further draw the Office's attention to new dependent Claims 11 and 12 which do not include an ester or instead include a cyclic ester.

Applicants thus submit that the rejection in view of Hall should be withdrawn.

The Office also rejected the claims as anticipated by a patent to Natoli (U.S. 5,585,412). As discussed above for Hall, Applicants submit that Natoli does not disclose an embedded or encapsulated inhibitor. Instead, Natoli, at best, discloses a blowing agent. Applicants submit that those of ordinary skill in the art understand that the blowing agent of Natoli is not the inhibitor of the present claims. For at least this reason, the rejection should be withdrawn.

Applicants further point out that the amendment to Claim 1 overcomes the rejection in view of Natoli at least because original Claim 7 was not over Natoli.

The Office also rejected the claims as anticipated by DE 10050417 (DE '417). For an unexplained reason, the Office is of the belief that the DE '417 publication qualifies as prior art under 35 U.S.C. § 102(e). Applicants submit that this is not the case and the rejection should therefore be withdrawn.

Moreover, the DE '417 reference is in a foreign language. Although the Office vaguely asserts that DE '417 discloses the features of the present claims, the Office cites to no specific disclosure of DE '417 and instead vaguely cites "the entire document".

DE '417 is in the German language. The Office provided no translation of DE '417 and appears to be merely relying upon the International Preliminary Examination Report as a basis for the rejection. Applicants draw the Office's attention to the unpublished opinion in *Ex parte Bonfils*, 64 USPQ2d 1456 (BPAI 2002) which sets out the Board's opinion with respect to the burden on the Office for providing translations in support of rejections made in view of foreign language documents. A copy of *Bonfils* is attached. As stated in *Ex part Bonfils*:

> When the examiner, as here, relies on a document that is in a foreign language, the examiner bears the burden of providing an English translation, at the latest, before forwarding the appeal to the board. Similarly, when the Applicant relies on a document that is in a foreign language for rebuttal of a rejection, the Applicant bears the burden of producing an

> English translation to support his position. In the past, the board has often expended the resources necessary to obtain a translation of a foreign language patent or technical article. When it did so, however, the burden of examining the claims with respect to that translation fell on the board in the first instance. Moreover, to the extent that the board relies on parts of a translation not previously provided to an applicant, any affirmance generally has to be a new ground of rejection under 37 CFR § 1.196(b)—which can result in further prosecution. Clearly, this procedure is inefficient and wastes the time and resources of the USPTO and Appellants.
>
> Efficient prosecution dictates that, when a rejection (or rebuttal) is founded on a document that is not in English, a translation be provided as soon as possible. When, as here, the Applicants can read and understand the reference, and when there appears to be no dispute about what the reference teaches, reliance on a translation provided to the board along with the examiner's Answer may not merit a new ground of rejection. When the Applicants or their representatives cannot read the non-English language, however, they may not be able to form an adequate understanding of the reference to rebut the rejection on the merits or to amend the claims to avoid the reference. In such cases, Applicants should insist that the examiner provide a translation before a final rejection is entered, seeking supervisory intervention if necessary. By the same token, if Applicants rely on a foreign language reference to rebut a rejection, the examiner may insist on a translation as a condition of a complete response, just as a declaration submitted in a foreign language, without a certified translation, would have no weight. We do not encourage pro forma objections: in some cases, the examiner and Applicants may be able to advance prosecution of a case without a translation. To the extent that the patentability of claims depends on a foreign language reference, however, the record will be incomplete and inadequate until a translation has been entered. In no case should an appeal reach the board without a translation of any foreign language reference relied on by either the examiner or the Applicant.

Here, the Office made no attempt to provide an English translation of the DE '417 publication. Further, the Office failed to provide any support for the rejection other than to broadly assert that the entire document discloses a composition that has inherent features that meet the limitations of the present claims. Applicants submit the rejection is thus defective

and should be withdrawn at least until an English translation of DE '417 is provided by the Office.

Moreover, as best Applicants can determine, DE '417 does not disclose encapsulated or embedded inhibitors. Instead, DE '417 discloses encapsulated catalysts that are not the inhibitor of the present application (see the Abstract of DE '417).

For the reasons discussed above, Applicants submit that all now-pending claims are in condition for allowance and respectfully request the withdrawal of the rejections.

Respectfully submitted,

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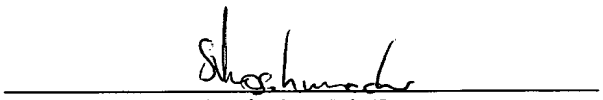
MAIER & NEUSTADT, P.C.
Norman F. Oblon



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64 USPQ2d 1456
Ex parte Bonfils
U.S. Patent and Trademark Office
Board of Patent Appeals and Interferences
Appeal No. 2001-2138
Decided February 20, 2002
Released August 27, 2002

Headnotes

PATENTS

[1] Practice and procedure in Patent and Trademark Office —Board of Patent Appeals and Interferences — Rules and rules practice (▶110.1105)

Patent examiner who relies on document that is in foreign language bears burden of providing English language translation thereof, at latest, before forwarding appeal to Board of Patent Appeals and Interferences, just as applicant who relies on document in foreign language for rebuttal of rejection must produce English translation in support of his or her position; although examiner and applicants may be able to advance prosecution of case without translation, to extent patentability of claims depends on foreign language reference, record will be incomplete and inadequate until translation has been entered, and in no case should appeal reach board without translation of any foreign language document relied upon by either examiner or applicant.

[2] Patentability/Validity — Obviousness — Relevant prior art — Particular inventions (▶115.0903.03)

There is no per se rule that claimed stereoisomer is obvious in view of disclosure of another

Page 1457

stereoisomer in prior art; in present case, patent examiner's rejection of claims for chemical compounds based on disclosure of stereoisomer of claimed compounds in prior art reference is reversed, since there is no evidence in record that ordinary steroid chemist would have expected that enantiomers of prior art compounds would be useful for controlling male fertility in mammals by affecting fertilizing power of spermazoid, as disclosed by applicants, or that said enantiomers would have any particular pharmacological activity.

Case History and Disposition

Appeal from examiner's rejection of claims in application for patent.

Patent application of Armelle Bonfils and Daniel Philibert, serial no. 08/403,276.[1] Applicants appeal from examiner's rejection of claims 1-5 for obviousness pursuant to 35 U.S.C. § 103(a). Reversed.

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[1] Application for patent filed March 13, 1995. Appellants claim priority under 35 U.S.C. § 119 to April 1, 1994, based on an application filed in France. The real party in interest is Roussel Uclaf, of Paris, France (Brief, Paper No. 18, at 1.)

[Editor's Note: The Board of Patent Appeals and Interferences has indicated that this opinion is not binding precedent of the board.]

Judge

Before William F. Smith, administrative patent judge, McKelvey, senior administrative patent judge, and Nagumo, administrative patent judge.

Opinion Text

Opinion By:

Nagumo, J.

ON BRIEF [2]

[2] Appellants, through counsel, requested an oral hearing. (Paper No. 20, filed May 6, 1998.) Our review of the case revealed that a hearing was not necessary to assist us in the resolution of the issues on appeal.

Decision on appeal under 35 U.S.C. § 134

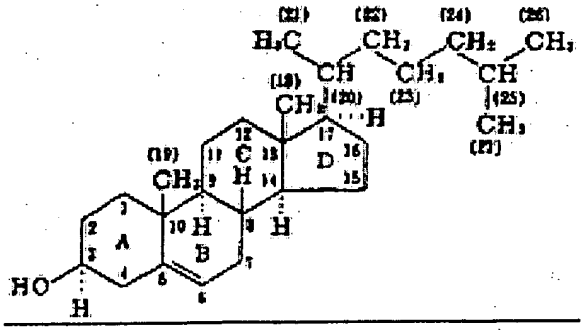
This appeal is from a decision of a primary examiner rejecting claims 1 through 5. Claim 6 has been withdrawn from consideration. We reverse.

A. Findings of fact

Background

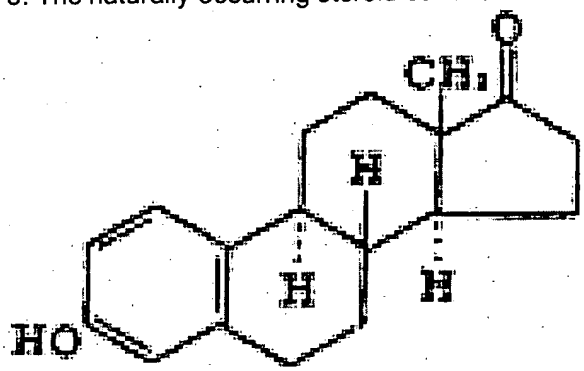
1. Compounds that are mirror images of one another are called "enantiomers." *See In re May*, 574 F.2d 1082, 1085, 197 USPQ 601, 603 (CCPA 1978) for a brief review of stereochemical terminology and conventions. Such compounds are also called "chiral" ('handed'), and "antipodal."(*E.g.*, Brief at 4.)

2. The standard numbering system for steroids is as follows:



(*Louis F. Fieser & Mary Fieser, Steroids* 1 (1959) ("*Fieser*").

3. The naturally occurring steroid estrone has the following stereochemistry:



Estrone

(*Fieser* at 464.)

An atom or group that lies below the plane of the paper is depicted by a dashed line leading to the group, and denoted "?" in the chemical name. An atom or group that lies above the plane of the paper is depicted by a solid line, dark triangles or thickened lines leading to the group, and denoted "?"in the chemical name. (*May* at 1085, 197 USPQ at 603.) Bonds to atoms or groups that can lie above or below the plane of the paper are denoted by wavy lines. (Spec. at 3, ll.6-9.)

The invention

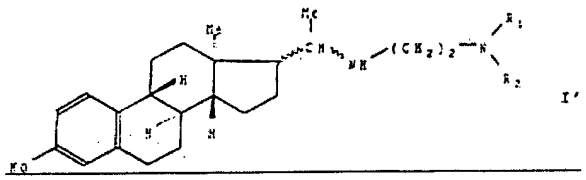
The record supports the following findings by at least a preponderance of the evidence.[3]

[3] To the extent these findings of fact discuss legal issues, they may be treated as conclusions of law.

4. The invention relates to certain stereoisomers of 20-substituted steroids, and their pharmaceutically acceptable salts. (Spec. at 2.)

5. According to Appellants, the compounds are useful for controlling male fertility in mammals *(id.)*, by affecting the fertilizing power of the spermazoid.(Spec. at 14, ll. 16-18.)

6. A preferred compound within the scope of Appellants' invention has the structure shown in formula I':



I'

where R_1 and R_2 are methyl.

7. This compound is named (20S) (8? 9?, 13?, 14?, 17?) 20-[((dimethylamino)-ethyl)-amino]-19-nor-?$^{1,3,5(10)}$-pregnatrien-3-ol. (Spec. at 5, II 10-12; claim 5.)

8. Comparison of the structure of formula I' with the structure of naturally occurring estrone shows that Appellants are claiming compounds wherein the B, C, and D fused rings are the mirror image of the naturally occurring estrone ring structure.

The claims

9. Claim 1 is representative and reads as follows:

A compound selected from the group consisting of a compound of the formula

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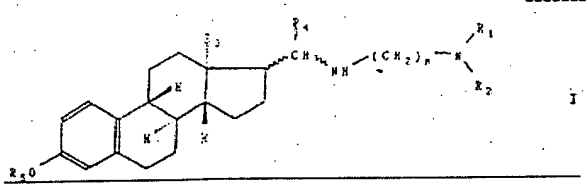

I

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wherein R_1 and R_2 are individually selected from the group consisting of alkyl of 1 to 12 carbon atoms and aralkyl of 7 to 15 carbon atoms or taken together form [sic, from] a saturated heterocycle of 5 to 6 ring members optionally having a second ring heteroatom selected from the group consisting of sulfur, oxygen and nitrogen, R_3 is an ?-alkyl of 1 to 8 carbon atoms, n is an integer from 2 to 15, R_4 is alkyl of 1 to 12 carbon atoms, R_5 is

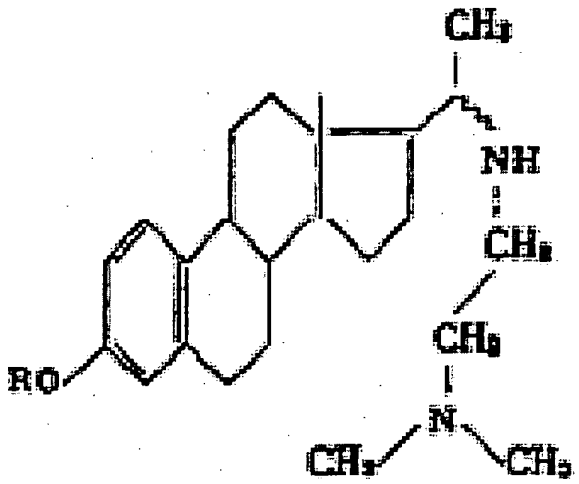
selected from the group consisting of hydrogen, alkyl of 1 to 12 carbon atoms and acyl of an organic carboxylic acid of up to 12 carbon atoms and the wavy lines indicate that the 17- and 20- asymmetrical centers are independent of the absolute R and S configurations and their non-toxic, pharmaceutically acceptable acid addition salts.

The examiner's rejections

10. Claims 1 through 5 were rejected under 35 U.S.C. § 103(a) as being unpatentable over French patent document 1,380,424 ("RU-I"), or French patent document 90,805 ("RU-II"), both assigned to Roussel-Uclaf. On receipt by the board, no translation for either document was present in the application file.

Roussel-Uclaf I

11. U.S. Patent No. 3,156,619, issued to Bertin and Nedélec on November 10, 1964 ("Bertin"), claims priority in part from RU-I. Although Bertin contains material not included in RU-I, the parallel cites *post* confirm the sense of the French text. We stress that the examiner did not cite Bertin, and that we use it as an informal translation to confirm our reliance on chemical formulas and names disclosed by RU-1.



12. RU-I concerns compounds having the structure:

where R represents hydrogen, a lower alkyl radical, or an acyl radical of a lower organic acid. (Roussel-Uclaf I at 1, left column;Bertin at col. 1, ll. 15-30.)

13. These compounds may be named 3-OR-20-(N,N-dimethylaminoethylamino)-19-nor-?$^{1,2,5(10)}$-pregnatrienes. (RU-I at 1, right column, ll.5-6; Bertin at col. 2, ll.69-70, and Table I at col. 3 (chemical reaction scheme).)

14. The compounds are disclosed to have antilipemic and hypocholesterolemiantic activities, and to lack any estrogenic activity. (RU-I at 1, left column, second paragraph; Bertin at col. 2, ll.40-43.)

15. The disclosed synthesis of the inventive compounds begins with compounds of formula II, such as 3-OR 20-oxo 19-nor ?$^{1,3,5(10)}$-pregnatriene.(RU-1 at 1, left column, last paragraph (see also the chemical scheme on the last page); Bertin at col. 2, ll.49-57.)

RU-II

16. RU-II concerns 11-hydroxy derivatives of the compounds disclosed by RU-I. These are compounds having the same structure as those of RU-1, with a hydroxy(-OH) group attached to the C-ring at the 11-position. (RU-II at 1, left column, lower chemical structure.)

The examiner's rationale

17. In the examiner's words, "[b]oth references teach 20-(?-N,N-dimethylaminoethyl)amino-19-nor-1,3,5(10)-pregnatrienes having either a hydroxy or an acyl group in the 3-position. (Answer at 3.)

18. The examiner finds that Appellants' claimed subject matter differs from the teachings of the reference by "having a different stereochemistry at the 8, 9, 13 and 14 positions." (*Id.* at 4.)

19. The examiner then observes that "the claimed compounds are stereoisomers of the compounds taught by the references." (*Id.*)

20. The examiner concludes that "[i]n the absence of unobvious results, a single isomer of a compound would be obvious to one having ordinary skill in the art." (*Id.*)

21. The examiner argues that the evidence of unexpected results presented by Appellants is unpersuasive because they did not provide side-to-side comparisons of the new enantiomer and the known enantiomer. Hence, according to the examiner, Appellants have not shown that "the two isomers would have different

properties or that the claimed compounds have some unexpected or superior property." (*Id.*)

Appellant's argument

22. In response to the first office action on the merits of the application rejecting claims 1-5 over RU-II, Appellants enclosed a copy of RU-I and stated:

"the compounds disclosed in the references have the normal stereochemistry of the

Page 1460

pregnane derivatives which is 8? 9? 13? 14? and in contrast thereto, the compounds of Applicants' invention have the *unusual* antipodal configuration of 8? 9? 13? 14?. This unnatural configuration of the steroids of Applicants' invention is obtained by a process in which the starting compound is the antipodal (-)-estrone (8? 9? 13?14?), whereas, the prior art compounds start with the natural (+)-estrone(8? 9? 13? 14?) in the reaction sequence. [Paper No. 7 at 2, emphasis original.]

23. Appellants argue that the references relied on by the Examiner do not teach Appellants' specific 8?, 9?, 13?, 14? configuration of steroids. (Brief at 3.)

24. Appellants also argue that the references fail because they do not enable those of ordinary skill in the art to make the claimed antipodal compounds.(*Id.* at 3-4.)

25. Appellants argue further that evidence of record (Crossley[4])shows that the pharmaceutical activity of a new single stereoisomeric form "is not obvious to envisage" compared to a known stereoisomeric form or a known racemic mixture. (Brief at 4.)

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[4] Roger Crossley, *The Relevance of Chirality to the Study of Biological Activity*, 48 *Tetrahedron* 8155, 8156, 8174, 8175 (1992), filed attached to Paper No. 14 on November 12, 1997.

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26. Appellants urge that one skilled in the art would not have been able to predict the discovered effect on spermazoid levels based on the known antilipemic activity of the reference compounds. (*Id.*)

27. Appellants conclude that the obviousness rejection fails.

B. Discussion

We shall not sustain the examiner's rejection, which is based on an inadequate evidentiary record, and which fails to establish a prima facie case of unpatentability.

The evidentiary record

Findings of fact and conclusions of law by the USPTO must be made in accordance with the Administrative Procedure Act, 5 U.S.C. § 706(A), (E) (1994). *Zurko v. Dickinson*, 527 U.S. 150, 158, 119 S.Ct. 1816, 1821, 50 USPQ2d 1930, 1934 (1999). Our reviewing court has held that findings of fact must be supported by substantial evidence within the record. *In re Gartside*, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000) ("Because our review of the Board's decision is confined to the factual record compiled by the Board ... the 'substantial evidence' standard is appropriate for our review of Board factfindings. *See* 5 U.S.C. § 706(2)(E).") In the present case, the absence of English translations of the French documents is a serious gap in the evidentiary record.

The examiner has relied on two French patent documents as evidence of unpatentability. In this case, it

appears that Appellants have not been disadvantaged in responding to the rejections, as they provided the documents[5] and are French nationals. Thus, we may presume they reviewed and understood the French-language documents. In reviewing the record presented on appeal, however, we cannot say the same of ourselves. If we were to rely strictly on the documents of record, we would be unable to make adequate factual findings regarding the teachings of the French language references, and what they would have meant to one of ordinary skill in the art. Thus, we would be unable to explain the evidentiary basis for our holding of affirmance or reversal. This alone is sufficient basis for reversal or remand.

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[5] RU-1 was filed with Paper No. 7 on August 1, 1996; RU-2 was filed with Paper No. 3 on April 3, 1995.

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[1] When the examiner, as here, relies on a document that is in a foreign language, the examiner bears the burden of providing an English translation, at the latest, before forwarding the appeal to the board. Similarly, when the Applicant relies on a document that is in a foreign language for rebuttal of a rejection, the Applicant bears the burden of producing an English translation to support his position. In the past, the board has often expended the resources necessary to obtain a translation of a foreign language patent or technical article. When it did so, however, the burden of examining the claims with respect to that translation fell on the board in the first instance. Moreover, to the extent that the board relies on parts of a translation not previously provided to an applicant, any affirmance generally has to be a new ground of rejection under 37 CFR § 1.196(b)—which can result in further prosecution. Clearly, this procedure is inefficient and wastes the time and resources of the USPTO and Appellants.

Efficient prosecution dictates that, when a rejection (or rebuttal) is founded on a document that is not in English, a translation be provided as soon as possible. When, as here, the Applicants can read and understand the

reference, and when there appears to be no dispute about what the reference teaches, reliance on a translation provided to the board along with the examiner's Answer may not merit a new ground of rejection. When the Applicants or their representatives cannot read the non-English language, however, they may not be able to form an adequate understanding of the reference to rebut the rejection on the merits or to amend the claims to avoid the reference. In such cases, Applicants should insist that the examiner provide a translation before a final rejection is entered, seeking supervisory intervention if necessary. By the same token, if Applicants rely on a foreign language reference to rebut a rejection, the examiner may insist on a translation as a condition of a complete response, just as a declaration submitted in a foreign language, without a certified translation, would have no weight. We do not encourage *pro forma* objections: in some cases, the examiner and Applicants may be able to advance prosecution of a case without a translation. To the extent that the patentability of claims depends on a foreign language reference, however, the record will be incomplete and inadequate until a translation has been entered. In no case should an appeal reach the board without a translation of any foreign language reference relied on by either the examiner or the Applicant.

In this case, unusual circumstances, described in the next section, permit an immediate resolution of this appeal.

The prima facie case of obviousness

In the following discussion, we shall refer only to RU-1, as the examiner and Appellants appear to treat them cumulatively, and because Bertin, a patent in the same "family"that claims priority, in part, on RU-1, provides some guidance. We feel this is a reasonable way to proceed because the examiner and Appellants do not appear to have disputed their characterizations of the references. Only the inferences and conclusions each draws from the references are in dispute.

The burden is on the examiner to establish a *prima facie* case of obviousness of the claimed subject matter over prior art references. *In re Deuel*, 51 F.3d 1552, 1557, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995). Only after that burden is met must the applicant come forward with arguments or evidence in rebuttal. *Id.* Findings of fact must be supported by substantial evidence in the record. *In re Gartside*, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). A rejection under § 103 is proper only when "the PTO establishes that the invention as claimed in the application is obvious over cited prior art, *based on the specific comparison of that prior art with claim limitations." In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995) (emphasis added).

The only fact relied on by the examiner in this appeal is that RU-1 discloses a stereoisomer of the claimed compounds. (*See* the Answer at 4;the final office action on the merits, Paper No. 12 at 2-3; and the first office action on the merits, Paper No. 8 at 3.) While a single disclosed chemical structure or formula might suffice as the *sole* evidence of unpatentability in a rejection under 35 U.S.C. § 102 for anticipation, such will rarely, if ever, suffice as substantial evidence of obviousness under § 103(a). This is because the examiner must explain why the differences would have been obvious, and the explanation must be supported by evidence in the record.

[2] In the present case, the examiner appears to have relied on a *per se* rule that a stereoisomer is obvious in view of a disclosure of another stereoisomer in the prior art. (Answer at 4.) This is error. *Ochiai* at 1572, 37 USPQ2d at 1133 ("reliance on *per se* rules of obviousness is legally incorrect and must cease.") Moreover, the cases cited by the examiner (Paper No. 8 at 3)do not support the examiner's position.

In the most recent case relied on by the examiner, *In re Deuel*, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995), the court explained that a *prima facie* case of obviousness based on structural similarity *may* arise *if* the "[s]tructural relations provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties." *Id.* at 1558, 34 USPQ2d at 1214. The court stressed that "[i]n the case before us there must be adequate support in the prior art for the...change in structure, in order to complete the PTO's *prima facie* case and shift the burden of going forward to the applicant." *Id., quoting In re Grabiak*, 769 F.2d, 729, 731-32, 226 USPQ 870, 872 (Fed. Cir. 1985). *See also, e.g., In re Payne*, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979) ("An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art

to make a claimed compound, in the expectation that compounds similar in structure will have similar properties."); *May*, 574 F.2d at 1094, 197 USPQ at 611 ("the basis of the prima facie case of obviousness, at least to a major extent, is based on the presumed expectation that compounds which are similar in structure will have similar properties."). Nothing in these cases supports the examiner's apparent position that the disclosure of one enantiomer is sufficient by itself to establish *a prima facie* case of obviousness of the other enantiomer. Where, as here, there is evidence of unpredictability (*e.g.*, Crossley), and no evidence of common pharmaceutical or biological properties [6], the "presumed expectation" of similar properties due to the similar structures is not well-founded.

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[6] We stress the absence of evidence predicting pharmaceutical or biological properties of the compounds because it is only in interactions with other chiral molecules that the properties of one enantiomer will differ from its mirror image: all properties of the enantiomers that involve interactions only with achiral molecules will be identical, by symmetry.

Examination of the remaining cases cited by the examiner shows that words that might be interpreted as

establishing a *prima facie* case of obviousness of a claimed stereoisomer over the enantiomer disclosed in the prior art are either *dicta* because they were not necessary for the disposition of the case, or they were made within the context of the record before the court, and are thus of limited general applicability.

In *In re Adamson*, 275 F.2d 952, 125 USPQ 233 (CCPA 1960) the court upheld an obviousness rejection of claims to "[a] laevo-isomer of a compound ... substantially separated from the dextro-isomer" over references disclosing the racemate, i.e., a mixture of equal amounts of the enantiomers. More specifically, the references disclosed synthetically produced compounds of the same formula claimed. A chemistry text taught that synthetically produced substances containing asymmetric carbon atoms responsible for optical activity are optically inactive due to the formation of equal amounts of the laevo- and dextro-isomers. *Adamson* at 953, 125 USPQ at 234. Adamson argued that the invention was patentable because they discovered that the prior art product was a racemate, i.e., comprised of optical isomers, that the isomers could be separated, and that there were unexpected results. The court rejected the first two arguments, finding that, in view of the textbook, one of ordinary skill in the art would have recognized the reference product to be a racemate, and would also know how to separate the isomers. *Id.* at 954-55, 125 USPQ at 235. Finally, the court found the evidence of unexpected results was not persuasive, and so affirmed the rejection. Because the court did not rely on the general proposition that one optical isomer is *prima facie* obvious over its enantiomer, *Adamson* does not stand for that proposition.

In *Brenner v. Ladd*, 247 F.Supp. 51, 147 USPQ 87 (D.D.C. 1965), the district court agreed that, "in the absence of unexpected or unobvious beneficial properties, an optically active isomer is unpatentable over either the isomer of opposite rotation or, as in this case, the racemic compound itself." *Id.* at 56, 147 USPQ at 91. The court's decision, however, appears to be based on its factual finding that the only disclosed utility for the compounds L-acl or L-acl.HCL was their use as intermediates in the production of L-lysine. *Id.* The court held, however, that this utility would have been obvious over a prior art teaching that DL-acl (the racemate) could be hydrolyzed to DL-lysine through the intermediate DL-acl.HCl. *Id.* In modern terminology, the court found that the only evidence of record showed that L-acl had similar properties to the known DL-acl, and held that the evidence supported a *prima facie* case of obviousness. The broad proposition is thus mere *dicta*, as it was unnecessary for the court's decision.

In *In re Anthony*, 414 F.2d 1383, 162 USPQ 594 (CCPA 1969), Anthony conceded a *prima facie* case of obviousness of the claims to d-and l-enantiomers over a prior art teaching of the racemate. *Id.* at 1386, 162 USPQ at 596. Thus, the issue was not in controversy, and the court's statements, which are limited to reporting the course of proceedings below, are *dicta*.

The examiner has not directed our attention to any evidence in the record that the ordinary steroid chemist would have expected that the enantiomers of the RU-1 compounds would have affected spermazoid activity, as disclosed by Appellants, or that the enantiomers would have any particular common pharmacological properties. Thus, the examiner has not shown that RU-1 provides any suggestion to make or use the claimed enantiomers. Accordingly, we reverse this rejection.

Appellants appear to urge that the failure of RU-1 to teach any utility for the claimed compounds, and the known unpredictable nature of the changes in activity, toxicity, and utility due to changes in chirality, require reversal of

the examiner's rejection. (Brief at 4.) To the extent that Appellants intend to argue that the examiner has not established any basis for concluding that one of ordinary skill in the art would have had a reasonable expectation that the claimed compounds would have similar biological properties as the reference compounds, we agree that a *prima facie* case of obviousness has not been established, and that the rejection must be reversed for this reason as well.

Further considerations

In the event of further prosecution, the examiner and Appellants should consider the following issues:

Information disclosure statement

The information disclosure statement filed April 3, 1995, in Paper No. 3, has not been initialed by the examiner, although the examiner checked a box on the first action, Paper No. 6, indicating that the Notice of Art Cited by Applicant, form PTO-1449, was attached to the action. The examiner should take appropriate action.

Potential new matter issues:

The examiner and Appellants should determine whether new matter has been entered into the specification in violation of 35 U.S.C. § 132. Appellants submitted amendments to the specification (Paper No. 10, at page 1), alleging that certain material was omitted due to an error of translation from their French priority document. (*Id.*, at page 3.) However, the foreign priority document does not appear to be incorporated by reference into Appellants' specification. Under 35 U.S.C. § 119, the benefit of priority is granted only to the extent that "the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country," i.e., to the extent that common subject matter is disclosed. Absent an explicit incorporation by reference, the foreign priority document is not available as antecedent basis for amendments to the specification or claims. *Ex parte Bondiou*, 132 USPQ 356, 358 (Bd. App. 1961) (changing disclosure from "four hours" to—four days—not permitted because it introduced new matter under 35 U.S.C. § 132); *see also* MPEP § 2163.07 (8th Ed., August 2001). The examiner and Appellants should determine whether support for the amendments exists in the specification as filed. *See In re Oda*, 443 F.2d 1200, 1205-06, 170 USPQ 268, 272 (CCPA 1971) (permitting corrections of translation errors, explaining that the amendments did not result in any change in the claimed subject matter, and that the evidence of record was sufficient to show that one skilled in the art would have appreciated not only the existence of error, but what the error was and how to correct it).

In claim 3, the definition of "n" appears to be superfluous because n does not appear in formula I'.

In claim 5, a left parenthesis appears to be missing in the bracketed portion of the chemical name: 20-[((dimethylamino)-ethyl)-amino] ....

C. Decision

The rejections are *reversed*.

D. Order

Upon consideration of the appeal, and solely for the reasons given, it is ORDERED that the decision of the examiner rejecting claims 1 through 5 is *reversed*.

FURTHER ORDERED that no time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED

- End of Case -